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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,229	06/26/2003	Manfred Bohn	3804.1596-01	4228

22852 7590 08/23/2005

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,229	BOHN ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/077194.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.J.D

DETAILED ACTION

Response to Arguments

Applicant's arguments filed October 29, 2004 have been fully considered but they are not persuasive. However, Applicant's arguments with respect to claims 14-29 have been considered but are moot in view of the new ground(s) of rejection(art rejections) due to the scope of the claims are now changed. The amended claims are now drawn to a method of treating seborrheic dermatitis whereas the original claims are drawn to a method of treating a patient in need of treatment for seborrheic dermatitis.

New Matter

Applicant argues that the specification has enough support for the claimed term "one phase" because the specification teaches the unique water solubility that allows for single phase compositions. For example, the solutions and transparent gels teach the single phase nature because multiple phased composition such as emulsions usually are not solutions nor transparent. The argument is not persuasive. As evidenced by numerous documents available in the art, emulsions can be "solutions" or transparent. See search result attached hereinwith. Therefore, the instant specification fails to describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The new matter rejection is maintained as follow.

Saint – Leger(US 5650145) or Lange(US 5132107)

Applicant argues that the rejections over these two arts should not be applied here, because applicant's claims now amended are drawn to a method of treating seborrheic dermatitis rather than a symptom of seborrheic dermatitis. The claimed invention relates to treating diseases whereas the prior art cited teach only the treatment of symptoms of the diseases but not diseases themselves. However, applicant's argument is not persuasive because of the reasons below.

Claims 14-29 are presented for the examination

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art towhich it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth thebest mode contemplated by the inventor of carrying out his invention.

2. The claim 24 recites "one phase" at page 10, line 18. However, there is no support found in the instant specification for the phrase whereas the instant specification teaches a various pharmaceutical preparations in the form of hair lotions, shampoos, liquid soaps, as well as cream and gel preparations at page 5, lines 24-28. However, the said formulations are not enough to support the claimed language. There is no sufficient evidence to convey to one of ordinary skill in the art that applicant was in possession of the claimed invention. Therefore, the claims fail to comply with the written description requirement.

Claim Rejections - 35 USC §102 or 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 14-29 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Saint-Leger(US 5,650,145) .

The claims are drawn to a method of treating seborrheic dermatitis using the composition consisting essentially of at least one 1-hydroxy-2-pyridone of general formula I as recited in the claim 14.

US'145 teaches a pharmaceutical composition containing octopirox as active agent. In example 6, US'145 describes a method for treating a male human patient with a composition applied to the scalp, resulting in a change in the seborrhea. US'145 discloses that "individuals evaluated the variations in their seborrhea, which could be increased, stable or reduced"(column 6, lines 23 and 24). In claim 6, the composition is in the form of various unit dosage forms such as gel, shampoo, foam, liquid soap, etc. Thus, one phase composition is anticipated or obvious by the teaching of the cited reference. Table II shows the results of that variation in seborrhea. Many of the individuals experienced reduced seborrhea or stable seborrhea. Therefore, US'145 is directed to a method for treating seborrheic dermatitis. In fact, US'145 teaches that antifungal(e.g. octopirox) is effectively inhibits or prevents the growth of yeasts, in particular those found at the surface of the epidermis which is rich in sebaceous glands and especially at the surface of the scalp such as for example, pityrosporum ovales.

As mentioned in board decision, most elements required by the instant claims are well taught by the cited reference.

Applicant's claims use transitional phrase" consisting essentially of" whereas US'145 uses two active agents(i.e. antifungal agent+ antibacterial agent), it does not render the calimed invention patentably distinct over the prior art of the record.

"Consisting Essentially Of"

Applicants amend the claims and argues that the pending claims 14-26 are patentably distinguish over Saint-Leger in view of the transition phrase "consisting essentially of"(Request for reconsideration and withdrawal of the rejection, see Remark). According to applicants, the recitation of an active component in those claims "consisting essentially of" 1-hydroxy-2-pyridones exclude an antibacterial agent.

The examiner disagree.

As stated in PPG Indus., Inc. V. Guardian Indus. Corp., 156 F 3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354(Fed. Cir. 1998),

By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising' format.(Emphasis added).

Here, applicants' argument that "consisting essentially of" excludes those antibacterials is an example of idse dixit reasoning. Applicants do not describe the "basic and novel properties of the invention," or explain why or establish how antibacterials of US'145 materially affects those properties.

Additionally, it is apparent from applicant's specification(page col.2, lines 17-23) that the composition of the claimed method may include a host of ingredients or additives such as keratolytics or keratoplastic agent(e.g. sulfur, salicylic acid), or alcohols(e.g. ethyl or isopropyl alcohols) . On this record, it is unclear why the antibacterials would "materially affect" the basic and novel properties of the invention and, accordingly, be excluded by the phrase "consisting essentially of," whereas the host of ingredients listed in the specification do not materially affect the basic and novel properties of the invention and, accordingly, are included by the phrase "consisting essentially of." Applicants have not made it clear, in their specification or in their request for reconsideration, what they "regarded as constituting a material change in the c the basic and novel properties of the invention."

Therefore, the claims 14 and 24 are anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Saint-Leger(US 5,650,145) .

Claims 19 adds a pH-llimitation to claim 14 which is not explicitly disclosed by Saint-Leger. As stated in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977):

> Where, as here, the claimed and prior ad products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior ad products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. j 102, on 'prima facie obviousness' under 35 U.S.C. j 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

Example I of Saint-Leger reasonably appears to include the free form of a l-hydroxy-z-pyridone, viz., OCTOPIROX, and an anionic surfactant. Applicants' specification states that when using the free form of the active ingredient, as Example 1 of Saint-Leger appears to be using, adjustment of pH to the skin-physiological range of approximately 4.5 to 6.5 is not necessary. (Specification, page 8, lines 29-33).

Thus, it reasonably appears that Saint-Leger's Example 1 composition necessarily or inherently has a PH within the pH range of the composition recited in claim 38 and would not need to be adjusted to meet that range.

Example 1 otherwise is identical to the claimed invention. On these facts, we believe that the evidence is sufficient to shift the burden of persuasion to applicants to show that the composition described in Example 1 of Saint- Leger does not necessarily or inherently have a PH within the range recited in claim 19.

In any event, it would have been apparent to any person having ordinary skill in the art that the recited PH would be inherent in, or an obvious modification of, Saint-Leger's composition for use in treating a symptom of seborrheic dermatitis because Saint-Leger's composition is "formulated in a topically physiologically acceptable medium." (Saint-Leger, abstract).

It is noted that the extrinsic evidence to support inherent feature(i.e. pH) is well documented in the publications, see PTO-892. As evidenced by numerous documents available in the art, for instance, the Lange(US5132107) patent teaches using a physiologicallyacceptable acid in its second treatment phase. (Lange, abstractl.; Lange

states thatthe second phase "comprises a physiologically acceptable acid component, or mixtureof such components." .

Lange explains (column 5, lines 33-38):

> The acidity of the phase 11 solution is generally adjusted in the area of PH 3-6, preferred 4-5. The acidity of the phase 11 composition is adjusted in such a way that after application a situation is reached which is as much as possible in agreement with the natural PH of the skin.

Claim 15,20 and 27 limit claim 14, 19 and 26 to at least one l-hydroxy-z-pyridone or formula (1) comprising a cyclohexyl radical in the R4 position.

Saint-Leger teaches that a suitable antifungal agent for formulation according to his invention is CYCLOPIROX, i.e., 6-cyclohexyl-l-hydroxy-4-methyl-z-tlHl-pyridone (column 2, lines 28 and 29). Saint-Leger thus describes the l-hydroxy-z-pyridone compound recited in claims 15, 20 and 27.

Claims 18 and 23 depend from claim 14 and 19, respectively and adds a limitation that "the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants:" In ourjudgment, that additional limitation does not serve to distinguish over Example 1 of Saint-Leger disclosing not only sodium lauryl ether sulfate containing 2.2 mol of ethylene oxide (anionic surfactant) but also coconut monoisopropanolamide (additional surfactant).

Double Patenting

3. As acknowledged by applicant in remarks at page 20, because the copending application has not been allowed, provisional double patenting rejection is maintained

until such time as claims have been allowed in one of the applications where applicant will determine whether or not to file a terminal disclaimer to obviate said double patenting rejection.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 14-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/077194(not available–board of appeal). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to same treatment of seborrheic dermatitis using 1-hydroxy 2-pyridone compounds having the same generic formula. Thus, the scope of the claimed subject matter is embraced by one to the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

1. No claim is allowed. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.

2. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
August 8, 2005
Art unit 1618